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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,901	10/18/1999	JENNIFER E. VAN EYK	1997-023-04U	2043

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/419,901	Applicant(s) VAN EYK ET AL.	
	Examiner Lisa V. Cook	Art Unit 1641	

-- Th MAILING DATE of this communication appears on th cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,15-28,31 and 34-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,15-28,31 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicants' response to the Office Action mailed January 7, 2003 (Paper #23, filed 6/9/03) is acknowledged. In response to amendment-F filed therein, the specification along with claims 25 and 27 were modified. While claims 8-14, 29-30, 32-33, and 42-68 were canceled without prejudice or disclaimer. Currently claims 1-28, 31, 34-50 & 56-68 are pending and under consideration.

OBJECTIONS MAINTAINED

Drawings

2. The drawings in this application are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948). Applicant is required to submit a proposed drawing correction in reply to this Office action.

Applicants have deferred corrective action to the drawings until allowance. Accordingly the objection is maintained.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

4. The information disclosure filed 4/14/00 has been considered as to the merits before First Action.

Applicants have not addressed items 3 and 4 above, therefore the objection is maintained.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. With respect to the rejection under 35 USC 112, first paragraph regarding the deposit requirement for Mab monoclonal antibodies 8I-7 and 2I-14, Applicants have provided support that the cited antibodies are commercially available from Spectral Diagnostics Inc. (identified as catalogue no. MA-1040 and MA-1010 respectively and both monoclonal are specific for cardiac troponin I). Accordingly the rejection of record in paper #22, item 12 is withdrawn.

6. With respect to the rejection under 35 USC 112, first paragraph regarding the Lack of Enablement Applicant has shown possession of Mab monoclonal antibodies 8I-7 and 2I-14 which were employed in the instant disclosure to practice the inventive method. Accordingly the rejection of record in paper #22, items 9 and 10 are withdrawn.

Declaration Under In re Katz

7. The Declaration by Jennifer E. Van Eyk filed on 6/9/03 under 37 CFR 1.131 is sufficient to overcome the McDonough et al. (Circulation Research, January 8/22, 1999, pages 9-20) reference.

Claim Rejections

8. With respect to the claim rejections under 35 U.S.C. 102/103, Applicants Declaration under In re Katz has overcome the McDonough et al. (Circulation Research, January 8/22, 1999, pages 9-20) reference. Thus the rejections of record in paper #22 are withdrawn.

The following rejections are withdrawn:

I. Claims 1, 8-10, 15-16, 19-21, and 34-37 are rejected under 35 U.S.C. 102(a) as being anticipated by McDonough et al. (Circulation Research, January 8/22, 1999, pages 9-20).

II. Claims 2-5, 7, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonough et al. (Circulation Research, January 8/22, 1999, pages 9-20) in view of Wicks et al. (US patent #5,834,220).

III. Claims 6, 11-14, 17-18, 22-28, 31, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonough et al. (Circulation Research, January 8/22, 1999, pages 9-20) in view of Wicks et al. (US patent #5,834,220) and in further view of Van Eyk et al. (US patent #6,248,549).

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-7, 15-28, 31, and 34-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Mab monoclonal antibodies 8I-7 and 2I-14, it does not reasonably provide enablement for any compound that specifically binds a myofilament protein modification product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The written description in this case only sets forth Mab monoclonal antibodies 8I-7 and 2I-14 and therefore the written description is not commensurate in scope with the claims drawn to any compound that specifically binds the myofilament protein modification product. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is several from its enablement provision (see page 115).

With the exception of Mab monoclonal antibodies 8I-7 and 2I-14, the skilled artisan cannot envision the detailed structure of the encompassed monoclonal antibodies and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The monoclonal antibody itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of a compound/seq.id/etc. by only their functional activity does not provide an adequate written description of the genus.

The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by a sequence, falling within the scope of the claimed genus.

At section B(1), the court states that "An adequate written description ...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention" There is insufficient description in the disclosure to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only the isolated Mab monoclonal antibodies 8I-7 and 2I-14, but not any all compounds that specifically bind the myofilament protein modification product, would meet the full breadth of the claims as required by the written description provision of 35 USC 112, first paragraph.

Response to Arguments

10. Applicants contend that they have cancelled the claims drawn to any compound that specifically binds the myofilament protein modification products. This argument was carefully considered but not found persuasive because the remaining claims and disclosure required antibody binding to practice the method. Only Mab monoclonal antibodies 8I-7 and 2I-14 are taught in the disclosure, hence the written description is not commensurate in scope with the claims drawn to any compound that specifically binds the myofilament protein modification product. Only Mab monoclonal antibodies 8I-7 and 2I-14 would meet the written description requirement.

Double Patenting

11. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-7, 15-28, 31, and 34-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/115,589. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to the assessment of muscle damage in a subject via the detection of myofilament protein modification products. The instant claims require that one of the products be a chemical adduct of a myofilament protein. This invention is encompassed in the claims of application number 09/115,589 wherein the claims read on any myofilament protein modification product (including chemical adducts).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-7, 15-28, 31 and 34-41 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/115,589 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented.

This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

With respect to the art rejection presented below: The disclosure merely teaches the detection of TnI as it relates to muscle damage. The examiner takes TnI to be a protein meeting the limitations of a myofilament protein modification product being a chemical adduct of a myofilament protein. See disclosure page 1-lines 17-22, page 4-lines 5-8, page 30, and page 50. Accordingly in order to promote compact prosecution the following art rejection is applied.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 15-16, 19-21, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (W0 94/27156).

Wicks et al. measure troponin I in a complex sandwich assay having immobilized solid phases for the purpose of assaying irreversible cardiac damage from biological samples such as blood. Specifically two binding partners are utilized, one capable of binding to troponin I and one binding partner specific for the C subunit of the troponin complex. (pages 2-5). The test provides rapid and specific measurement of troponin I and is useful in confirming the diagnosis of myocardial damage.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 2-5, 7, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wicks et al. (W0 94/27156) in view of Wicks et al. (US patent #5,834,220)

Wicks et al. (W0 94/27156) is set forth above.

Wicks et al. (W0 94/27156) or Takahashi et al. (W0 96/10078) differ from the instant invention in not teaching an assessment of muscle damage employing the measurement of two different myofilament protein modification products.

However, Wicks et al. teach method for assaying for cardiac troponin I along with troponoin C. See abstract. The process and test system provide rapid and specific measurements of troponin I and is highly suitable for confirming the diagnosis of myocardial damage (reading on muscle damage).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure two different myofilament product degradation products (troponin I and troponin C) in muscle damage as taught by Wicks et al. in the method of Wicks et al. (W0 94/27156) involving troponin I analysis because Wicks et al. taught that Troponin I is one of three subunits of the troponin complex.

The other two subunits (designated T and C) are also immobilized on the thin myofilaments along with troponin I in both cardiac and skeletal muscle tissue. Column 1., lines 23-40. The utility of both troponin I and troponin C allowed for further distinction between cardiac muscle damage or skeletal muscles damage. See column 2, lines 37-49.

One having ordinary skill in the art would have been motivated to do this to acquire the enhanced sensitivity and ability to reduce false positives while providing more data sets for analysis, wherein accurate and precise detection is available.

The patent of Van Eyke et al. was employed as prior art because priority was not claimed to the patented invention. The patent also contains a different inventive entity.

II. Claims 6, 11-14, 17-18, 22-28, 31, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wicks et al. (W0 94/27156) in view of Wicks et al. (US patent #5,834,220) and in further view of Van Eyk et al. (US patent #6,248,549)

Please see Wicks et al. (W0 94/27156) in view of Wicks et al. as set forth above.

Wicks et al. (W0 94/27156) in view of Wicks et al. differ from the instant invention in not teaching an assessment of muscle damage employing two different myofilament protein modification products from different proteins involving phosphorylation.

However, Van Eyk et al. teach method for assaying for muscle damage (contractile state). Including heart failure and myocardial stunning. See abstract. In one embodiment PAK kinase activity is assessed by measuring the phosphoryaltion of two different proteins (troponin I and calponin for example) see column 3, lines 30-39 and claim 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure two different myofilament product degradation products from different protein with respect to their phosphorylation states (troponin I and Calponin) in muscle damage as taught by Van Eyk et al. in the method of Wicks et al. (W0 94/27156) in view of Wicks et al. to detect troponin I analysis because Van Eyk et al. taught that such method configurations allowed for the assessment of compositions in a screening format for their effect on PAK kinase activity or expression with respect to muscle disorders. See column 3, lines 1-39.

16. For reasons aforementioned, no claims are allowed.

Remarks

17. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Takahashi et al. (W0 96/10078) disclose methods for detecting myosin light chain 1 (MLC-1) as an indication of cardiac damage. The assay is conducted in biological sample like blood. (see pages

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4556, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
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8/22/03

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